sample in sufficient 1.0 percent potassium phosphate buffer, pH 6.0 (solution 1), to obtain a stock solution of convenient concentration; also, if it is packaged for dispensing, reconstitute as directed in the labeling. Then using a suitable hypodermic needle and syringe, remove all of the withdrawable contents if it is represented as a single dose container, or if the labeling specifies the amount of potency in a given volume of the resultant preparation, remove an accurately measured representative portion from each container. Dilute with solution 1 to obtain a stock solution of convenient concentration. Remove an aliquot of the stock solution, add sufficient hydrochloric acid so that the amount of acid in the final solution will be the same as in the reference concentration of the working standard and further dilute with solution 1 to the reference concentration of 1.0 unit of bacitracin per milliter (estimated).

(2) *Sterility.* Proceed as directed in §436.20 of this chapter, using the method described in paragraph (e)(1) of that section.

(3) *Pyrogens.* Proceed as directed in §436.32(a) of this chapter, using a solution containing 300 units of bacitracin per milliliter.

(4) [Reserved]

(5) *Loss on drying.* Proceed as directed in §436.200(b) of this chapter.

(6) *pH.* Proceed as directed in §436.202 of this chapter, using an aqueous solution containing 10,000 units per milliliter.

(7) *Residue on ignition.* Proceed as directed in §436.207(a) of this chapter.

(8) *Identity.* Proceed as directed in §436.319 of this chapter.

(9) *Heavy metals.* Proceed as directed in §436.208 of this chapter.

[42 FR 27229, May 27, 1977, as amended at 50 FR 19920, May 13, 1985]

§448.13 Bacitracin zinc.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Bacitracin zinc is the zinc salt of a kind of bacitracin or a mixture of two or more such salts. It is so purified and dried that:

(i) Its potency is not less than 40 units per milligram.

(ii) [Reserved]

(iii) Its loss on drying is not more than 5 percent.

(iv) Its pH is not less than 6.0 and not more than 7.5.

(v) Its zinc content is not more than 10 percent by weight on an anhydrous basis.

(vi) It passes the identity test.

(2) *Labeling.* In addition to the labeling requirements of §432.5 of this chapter, each package shall bear on the outside wrapper or container and the immediate container the statement ''For use only in the manufacture of nonparenteral drugs''.

(3) *Requests for certification; samples.* In addition to complying with the requriements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, loss on drying, pH, zinc content,and identity.

(ii) Samples required: 10 packages, each containing approximately 1.0 gram.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed in §436.105 of this chapter, preparing the sample for assay as follows: Dissolve an accurately weighed sample (usually 25 to 35 milligrams) in sufficient 0.01*N* hydrochloric acid to give a bacitracin concentration of 100 units per milliliter (estimated). Further dilute an aliquot with solution 1 to the reference concentration of 1.0 unit of bacitracin per milliliter (estimated).

NOTE: The final sample solution must contain the same amount of hydrochloric acid as the reference concentration of the working standard.

(2) [Reserved]

(3) *Loss on drying.* Proceed as directed in §436.200(b) of this chapter.

(4) *pH.* Proceed as directed in §436.202 of this chapter, using a saturated solution (approximately 100 milligrams of the sample per milliliter).

(5) *Zinc content.* Proceed as directed in §436.312 of this chapter.

(6) *Identity.* Proceed as directed in §436.319 of this chapter.

[42 FR 27229, May 27, 1977, as amended at 50 FR 19920, May 13, 1985]

§448.13a Sterile bacitracin zinc.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality,*

and purity. Sterile bacitracin zinc is the zinc salt of a kind of bacitracin or a mixture of two or more such salts. It is so purified and dried that:

(i) It contains not less than 40 units of bacitracin per milligram.

(ii) It is sterile.

(iii) [Reserved]

(iv) Its loss on drying is not more than 5.0 percent.

(v) Its pH is not less than 6.0 and not more than 7.5.

(vi) Its zinc content is not more than 10 percent by weight on a moisture-free basis.

(vii) It passes the identity test.

(2) *Labeling.* In addition to the labeling requirements of §432.5 of this chapter, each package shall bear on the outside wrapper or container and the immediate container the statement ''For use in the manufacture of topical drugs only''.

(3) *Requests for certification; samples.* In addition to the requirements of §431.1 of this chapter, each such request shall contain:

(i) Results of tests and assays on the batch for potency, sterility, loss on drying, pH, zinc content, and identity.

(ii) Samples required:

(*a*) For all tests except sterility: Six packages, each containing approximately 1.0 gram.

(*b*) For sterility testing: 20 packages, each containing approximately 500 milligrams.

(b) *Tests and methods of assay*—(1) *Potency.* Proceed as directed for bacitracin in §436.105 of this chapter, except add to each standard response line concentration sufficient 0.01*N* hydrochloric acid to yield the same ratio of 0.01*N* hydrochloric acid to 1 percent potassium phosphate buffer, pH 6.0 (solution 1) as present in the sample solution diluted to the reference concentration. Prepare the sample for assay as follows: Dissolve an accurately weighed sample (usually 25 to 35 milligrams) in sufficient 0.01*N* hydrochloric acid to give a bacitracin concentration of 100 units per milliliter (estimated). Further dilute with solution 1 to the reference concentration of 1.0 unit of bacitracin per milliliter (estimated).

(2) *Sterility.* Proceed as directed in §436.20 of this chapter, using the method described in paragraph (e)(1) of that section, except use diluting fluid F in lieu of diluting fluid A.

(3) [Reserved]

(4) *Loss on drying.* Proceed as directed in §436.200(b) of this chapter.

(5) *pH.* Proceed as directed in §436.202 of this chapter, using a saturated solution (approximately 100 milligrams of the sample per milliliter).

(6) *Zinc content.* Proceed as directed in §436.312 of this chapter.

(7) *Identity.* Proceed as directed in §436.319 of this chapter.

[39 FR 19115, May 30, 1974, as amended at 40 FR 15088, Apr. 4, 1975; 40 FR 19194, May 2, 1975; 42 FR 27230, May 27, 1977; 50 FR 19920, May 13, 1985]

§448.15a Sterile capreomycin sulfate.

(a) *Requirements for certification*—(1) *Standards of identity, strength, quality, and purity.* Sterile capreomycin sulfate is the amorphous sulfate salt of capreomycin. It is a white or essentially white powder. Capreomycin has been separated chromatographically into components designated capreomycins Ia, Ib, IIa, and IIb. Each component has been partially characterized according to its type and amino acid content. Capreomycin Ia contains serine and no alanine. Capreomycin Ib contains alanine and no serine. Capreomycin I is a mixture of capreomycins Ia and Ib. It is so purified and dried that:

(i) Its potency is not less than 700 micrograms and not more than 1,050 micrograms of capreomycin per milligram on an ''as is'' basis. If it is packaged for dispensing, its potency is satisfactory if it is not less than 90 percent and not more than 115 percent of the number of milligrams of capreomycin that it is represented to contain.

(ii) It is sterile.

(iii) [Reserved]

(iv) It is nonpyrogenic.

(v) It contains no depressor substance.

(vi) Its loss on drying is not more than 10 percent.

(vii) Its pH in an aqueous solution containing 30 milligrams per milliliter (or if packaged for dispensing, after reconstitution as directed in the labeling) is not less than 4.5 and not more than 7.5.